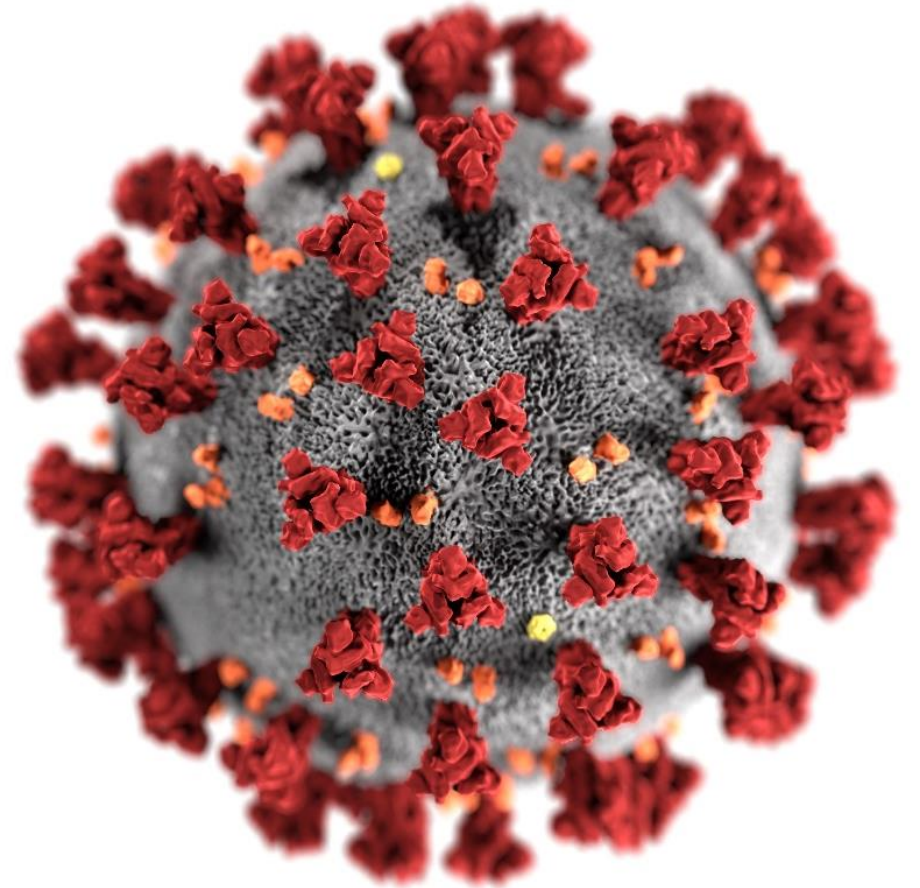


# ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

October 30, 2020



# Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings
- At the September 22<sup>nd</sup> meeting, ACIP reviewed:
  - Overview of COVID-19 vaccine safety
  - Enhanced vaccine safety surveillance
  - Vaccine implementation
  - Disparities among COVID-19 epidemiology
  - Overview of vaccine equity and prioritization frameworks
  - Phase 1 allocation for COVID-19 vaccine: Work Group considerations

# COVID-19 Work Group activities – October 2020

- COVID-19 Vaccine Work Group meets weekly
  
- Topics covered in October:
  - Review of available information on reinfection of COVID-19
  - Post-infection immunity
  - Discussions to finalize the Outcomes for GRADE
  - Modeling data for initial allocation of vaccine
  - Current epidemiology of COVID-19 in pregnant women
  - Review of ethical principles to inform initial allocation of vaccine
  - Clinical development program for two COVID-19 vaccines, including data from Phase I/II clinical trials and plans for Phase III clinical trials
  - Further discussions regarding COVID-19 vaccine allocation

# Today's agenda

## Vaccine Development & Regulatory

- **Update from VRBPAC meeting:**  
Dr. Doran Fink (FDA)
- **NVX-CoV2373 Vaccine Candidate:**  
Dr. Filip Dubovsky (Novavax)
- **Janssen's SARS-CoV-2 Vaccine Program:**  
Dr. Jerry Sadoff (Janssen)

## Implementation

- **Update on vaccine implementation planning:**  
Dr. Janell Routh (CDC)
- **Vaccinate with Confidence:**  
Dr. Amanda Cohn (CDC)

## Safety

- **FDA safety surveillance systems:**  
Dr. Steven Anderson (FDA)
- **Post-authorization safety monitoring plans:**  
Dr. Tom Shimabukuro (CDC)

## Allocation and Epidemiology

- **Modeling strategies for the initial allocation of COVID-19 vaccines:** Dr. Matthew Biggerstaff (CDC)
- **Updates to immunity and epidemiology to inform COVID-19 vaccine policy:** Dr. Megan Wallace (CDC)
- **Ethical principles for early vaccine allocation:**  
Dr. Mary Chamberland (CDC)

## Work Group Interpretation

- **Work Group interpretation of data:** Dr. Sara Oliver (CDC)
- **Policy questions, Evidence to Recommendation Framework, and outcomes:** Dr. Kathleen Dooling (CDC)

# Vaccine Update

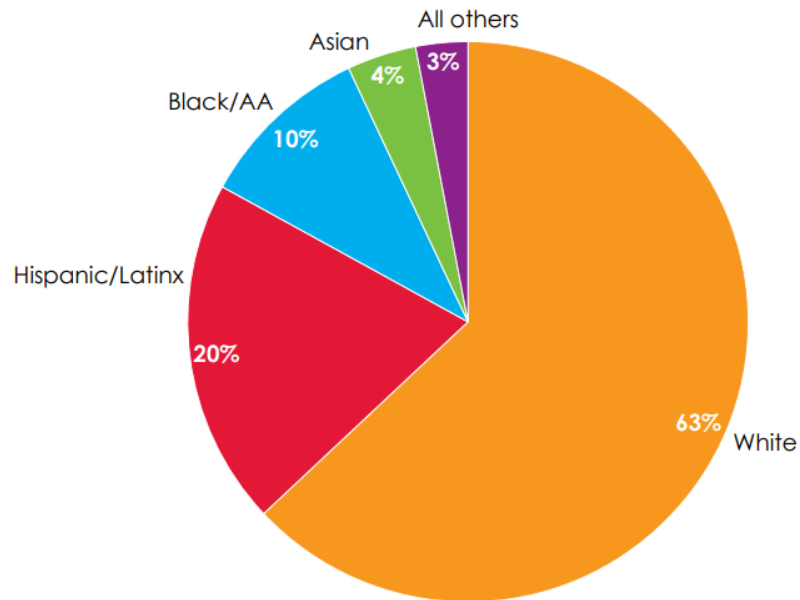
- Over 200 COVID-19 vaccines currently under development
- Within the United States:
  - **Four** vaccines in active Phase III clinical trials
  - **Five** vaccines in active Phase I/II clinical trials

# Vaccine Update: Phase III clinical trials in the U.S.

- AZD1222 vaccine (AstraZeneca) announced removal of FDA hold 10/23, resuming Phase III trials
- Ad26.COV2.S vaccine (Janssen) announced lifting of safety pause 10/23, resuming Phase III trials
- BNT162b2 vaccine (Pfizer/BioNtech)
  - **42,133** participants enrolled as of 10/26/2020
  - 35,771 participants have received their second vaccination
  - 30% of U.S. participants enrolled have “diverse backgrounds”
- mRNA-1273 vaccine (Moderna): ***Enrollment Complete***
  - **30,000** participants enrolled as of 10/22/2020
  - 25,654 participants have received their second vaccination

# Vaccine Update: Phase III clinical trials in the U.S.

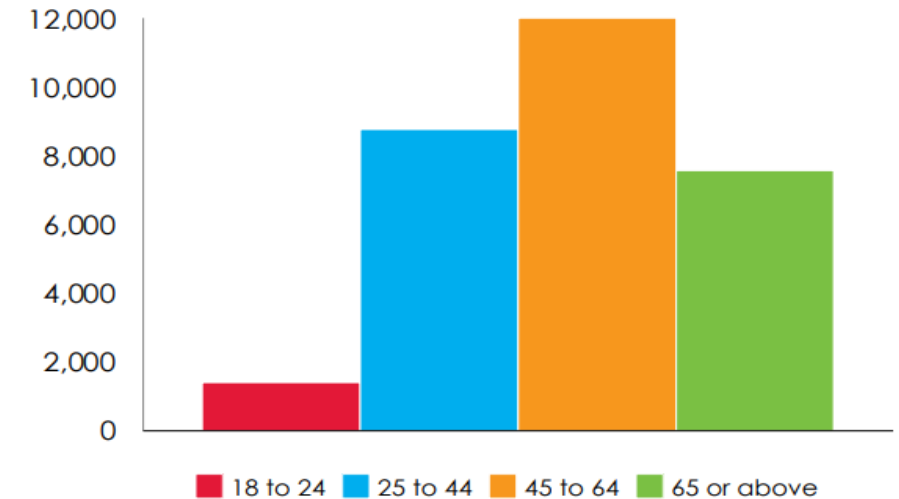
## Race and ethnicity



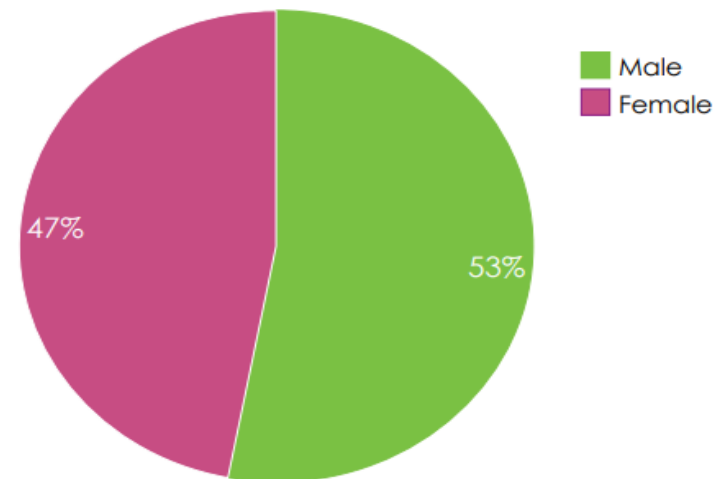
**22% healthcare personnel**

**27%** of participants living with comorbidities:  
including diabetes, cardiac disease,  
lung disease, obesity

Cove Study age breakdown



Cove Study gender distribution



## Age and gender

moderna

# COVID-19 vaccines in human clinical trials – United States\*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	<ul style="list-style-type: none"> <li>2 doses (0, 28d)</li> <li>IM administration</li> <li>18-55, 56+ years</li> </ul>	NCT04470427	Enrollment complete
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	<ul style="list-style-type: none"> <li>2 doses (0, 21d)</li> <li>IM administration</li> <li>18-85 years</li> </ul>	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	<ul style="list-style-type: none"> <li>2 doses (0, 28d)</li> <li>IM administration</li> <li>≥18 years</li> </ul>	NCT04516746	✓
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	III	<ul style="list-style-type: none"> <li>1 dose</li> <li>IM administration</li> <li>18-55, 65+</li> </ul>	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	<ul style="list-style-type: none"> <li>Single or 2 doses</li> <li>IM administration</li> <li>18-49, 50+</li> </ul>	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II	<ul style="list-style-type: none"> <li>2 doses (0, 21d)</li> <li>IM administration</li> <li>18-84</li> </ul>	NCT04368988	Enrollment complete
V591	Merck	Viral Vector	I/II	<ul style="list-style-type: none"> <li>2 doses (1, 57d)</li> <li>IM administration</li> <li>18-55</li> </ul>	NCT04498247	✓

\*As of October 27, 2020

\*\*Currently on hold in US

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccine.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccine.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>





# COVID-19 vaccines in human clinical trials – United States\*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
AV-COVID-19	Aivita	AuDendritic cell	I/II	<ul style="list-style-type: none"> <li>1 dose</li> <li>18+</li> </ul>	NCT04386252	Not yet recruiting
VXA-CoV2-1	Vaxart	Viral vector (NR)	I	<ul style="list-style-type: none"> <li>2 doses (1, 29d)</li> <li>Oral tablet</li> <li>18-54</li> </ul>	NCT04563702	✓
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	<ul style="list-style-type: none"> <li>2 doses (0, 4w)</li> <li>SC administration/ electroporation</li> <li>≥18 years</li> </ul>	NCT04336410	Active, not recruiting

\*As of October 27, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccine.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccine.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting\*

## Inactivated Vaccines

*3 inactivated vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BIBP/Sinopharm BBIBP-CorV	Beijing Institute of Biological Products/Sinopharm	Inactivated	Argentina	Phase III	NCT04560881
Sinovac CoronaVac	Sinovac/Instituto Butantan	Inactivated	Turkey, Brazil, Indonesia	Phase III	NCT04582344; NCT04456595; NCT04508075
WIBP vaccine	Wuhan Institute of Biological Products/Sinopharm	Inactivated	Morocco	Phase III	ChiCTR2000039000
WIBP/BIBP/Sinopharm vaccines	Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm	Inactivated	UAE, Bahrain, Jordan, Egypt	Phase III	NCT04510207

## Protein Subunit Vaccines

*10 protein subunit vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Novavax NVX-CoV2373	Novavax	Protein subunit	UK	Phase III	NCT04583995

\*As of October 19, 2020

Sources: <https://millkeninstitute.org/covid-19-tracker>; <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccine.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccine.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting\*

## Viral Vector Vaccines (non-replicating)

*7 non-replicating viral vector vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Cansino Ad5-nCoV	CanSino Biological Inc/ Beijing Institute of Biotechnology	Non-replicating viral vector	Pakistan, Russia	Phase III	NCT04526990; NCT04540419
Gamaleya Gam-COVID- Vac	Gamaleya Research Institute	Non-replicating viral vector	Belarus, Russia	Phase III	NCT04530396; NCT04564716
Janssen Ad26.COV2.S	Janssen Pharmaceutical Companies	Non-replicating viral vector	USA, Argentina, Brazil, others	Phase III	NCT04505722
Oxford ChAdOx1-S	University of Oxford/AstraZeneca	Non-replicating viral vector	UK, Brazil, India	Phase II/III	NCT04400838; NCT04536051; CTRI/2020/08/027170

## RNA Vaccines

*7 RNA vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BioNTech BNT162 (b1/b2)	BioNTech/Fosun Pharma/Pfizer	RNA	USA, Argentina, Brazil, others	Phase II/III	NCT04368728



\*As of October 19, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker/>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccineshinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

# Work group members

## ACIP members

- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

## Ex-officio/government members

- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

## CDC Co-leads

- Kathleen Dooling
- Sara Oliver

## Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

## Liaisons, cont’d

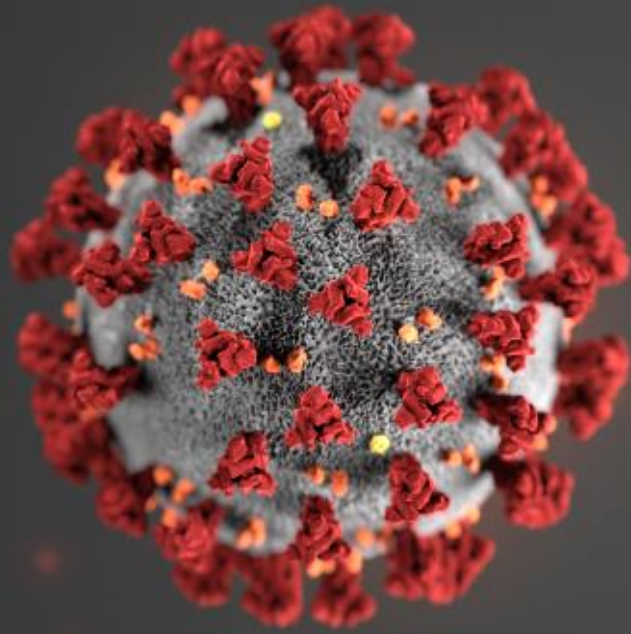
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao(alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

## Consultants

- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)

# CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

# Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

